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NOTICE OF ALLOWANCE AND FEE(S) DUE

21559 7590 11/26/2008

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 11/26/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,645	02/10/2005	Claude Prigent	50376/004001	7358

TITLE OF INVENTION: ANTI-AURORA-A MONOCLONAL ANTIBODY, METHOD FOR OBTAINING SAME AND USES THEREOF FOR DIAGNOSING AND TREATING CANCERS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$300	$0	$1810	02/26/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

21559 7590 11/26/2008

CLARK & ELBING LLP
101 FEDERAL STREET
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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,645	02/10/2005	Claude Prigent	50376/004001	7358

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nonprovisional	NO	$1510	$300	$0	$1810	02/26/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
BRISTOL, LYNN ANNE	1643	435-007230

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 286 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 286 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

Notice of Allowability	Application No.	Applicant(s)	
	10/517,645	PRIGENT ET AL.	
	Examiner	Art Unit	
	LYNN BRISTOL	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the Response of 10/1/08 to the Office Action of 7/7/08*.

2. ☒ The allowed claim(s) is/are *42-52 and 55*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/David J Blanchard/
Primary Examiner, Art Unit 1643

DETAILED ACTION

1. Claims 42-52 and 55 are all the pending claims for this application and under examination.

2. Claims 26-41 were cancelled and new claims 42-55 were added in the Response of 10/1/08.

3. Claims 53 and 54 are cancelled by Examiner's Amendment discussed below.

4. The examiner thanks Applicants' representative, Ms. Michaud, for the telephone interviews of 11/17/08 and 11/20/08 in order to advance prosecution.

Withdrawal of Objections

Claim Objections

5. The objection to Claims 26-37 for inconsistent recitations, e.g., aurora-A or aurora-A protein or aurora-A kinase is moot for the cancelled claims.

6. The objection to Claim 31 for reciting the term "vector" instead of "vehicle" is moot for the cancelled claim

7. The objection to Claims 32-34 for reciting "a method for in vitro diagnostic or prognostic of cancers" is moot for the cancelled claims.

8. The objection to Claim 36 for omitting to include a comma after the term "respectively" in line 3 is moot for the cancelled claim.

Withdrawal of Rejections

Claim Rejections - 35 USC § 101

9. The rejection of Claims 26-37 for being directed to an antibody found in nature is moot in view of the cancelled claims.

10. The rejection of Claims 32-34 as being drawn to non-statutory subject matter for a “use” of the antibody in a method for diagnosing or prognosing cancers without reciting the method steps for performing the intended endpoint is moot for the cancelled claims.

Claim Rejections - 35 USC § 112, second paragraph

11. The rejection of Claim 27 in lacking antecedent basis for the limitation "where aurora-A protein is secreted" in line 4 is moot for the cancelled claim.

12. The rejection of Claims 32-37 in lacking antecedent basis for the limitation “a monoclonal antibody according to claim 26” in line 2 of Claim 32; line 3 of Claim 35; and line 3 of Claim 37 is moot for the cancelled claims.

13. The rejection of Claims 35-37 for the recitation “if appropriate” in lines 4 and 5 of Claim 35 and in line 4 of Claim 37 is moot for the cancelled claims.

14. The rejection of Claim 35 for reciting a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is moot for the cancelled claim.

15. The rejection of Claims 35-37 in lacking antecedent basis for the limitation "in the complexes formed during the preceding stage" in Claim 35 is moot for the cancelled claims.

16. The rejection of Claims 35-37 for the recitation “this, if necessary, after appropriate rinsing of the solid support” in the last line of claim 35 is moot for the cancelled claims.

17. The rejection of claims 33, 34 and 37 for the phrase "such as" is moot for the cancelled claims.

18. The rejection of Claim 36 for the recitation “the determination of a quantity of aurora-A protein lower or greater than the normal physiological values in the biological sample" is moot for the cancelled claim.

19. The rejection of Claim 37 for reciting a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is moot for the cancelled claim.

EXAMINER'S AMENDMENT

20. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Susan Michaud on 11/20/08.

The application has been amended as follows:

43. (Currently Amended) The 35C1 antibody of claim 42, wherein said antibody can be fixed on membranes containing human or murine aurora-A protein kinase, allows detection and purification of human and murine aurora-A protein kinase by immunoprecipitation, allows staining of biological tissues where the human or murine aurora-A protein is secreted, and does not inhibit the enzymatic activity of human and murine aurora-A protein kinase; and wherein said 35C1 antibody is obtained by the following steps:

a) five injections spread over fifteen days to mice of recombinant aurora-A protein kinase ~~produced by E. coli bacteria transformed with a bacterial expression vector, with human cDNA coding for aurora-A protein kinase having been inserted in the genome of said bacterial expression vector~~, sacrificing said mice, and fusing spleen cells of said mice with hamster cells immortalized in culture in order to obtain hybridomas.

wherein said recombinant aurora-A protein kinase is produced by E. coli bacteria transformed with a bacterial expression vector, with human cDNA coding for aurora-A protein kinase having been inserted in the genome of said bacterial expression vector;

b) screening of said hybridomas producing an antibody capable of irmnunoprecipitating said recombinant aurora-A protein kinase, and recovery of said positive hybridomas after this first screening;

c) screening of said hybridomas recovered in step b), producing an antibody capable of immunoprecipitating endogenous aurora-A protein kinase from an extract of human HeLa cells in culture, and recovery of said positive hybridomas after this second screening;

d) screening of said hybridomas recovered in step c), producing an antibody capable of recognizing in indirect immtmofluorescence centrosomes and poles of the mitotic spindle of human cells in culture, and recovery of said positive hybridomas after this third screening;

e) screening of said hybridomas recovered in step d), producing an antibody capable of immunoprecipitating said endogenous aurora-A protein kinase of mice from an extract of murine cells in culture, and recovery of said positive hybridomas after this fourth screening;

f) screening of said hybridomas recovered in step e), producing an antibody capable of recognizing in indirect immunofluorescence centrosomes and poles of the mitotic spindle of murine cells in culture; and

g) recovery and purification by cloning of a positive hybridoma after screening step f), and production of said 35C1 antibody.

48. (Currently Amended) An *in vitro* diagnostic or prognostic method for cancers, in a human~~s~~ or an animal~~s~~, characterized in that it comprises:

- placing the 35C1 antibody of claim 42 in the presence of a biological sample taken from ~~an individual~~ said human or said animal,

-detection of aurora-A protein kinase that may be present in the biological sample using marked reagents recognizing either said 35C1 antibody linked to said aurora-A protein kinase, or the aurora-A protein kinase linked to said 35C1 antibody which may be present in the biological sample.

52. (Currently Amended) A kit for the implementation of the diagnostic method of claim 48, characterized in that it comprises ~~the~~ an isolated 35C1 antibody ~~of claim 42~~.

53. (Cancelled)

54. (Cancelled)

55. (Currently Amended) The kit of claim ~~54~~ 52, ~~characterized in that said marker is~~ further comprising an anti-PCNA antibody.

Examiner's Statement of Reasons for Allowance

21. The following is an examiner's statement of reasons for allowance: A hybridoma clone deposited under CNCM accession no. I-3050 is found to be free of the prior art and fully supported by the instant specification. The 35C1 antibody produced by the hybridoma is novel and nonobvious. A kit comprising the 35C1 antibody for diagnosing or prognosing a cancer, and a pharmaceutical composition the 35C1 antibody is found to be free of prior art. The in vitro diagnostic or prognostic method for cancer comprising the 35C1 antibody is found to be free of prior art and enabled.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

22. Claims 42-52 and 55 are allowed.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LAB

/David J Blanchard/
Primary Examiner, Art Unit 1643